REMARKS

Claim Rejections – 35 U.S.C. § 112, first paragraph

The Office Action rejects claims 1-30 under 35 U.S.C. 112, first paragraph, because the specification allegedly does not enable cloning of primates, or nuclear transfer using isolated chromosomes. In response to this rejection, Applicant has amended the claims so that they no longer cover cloning of primates, and to require that the donor genetic material is present in a cell or nucleus. Based upon these amendments, Applicant respectfully requests withdrawal of the enablement rejections of claims 1-30.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action rejects claims 1-5, 11, 14, 16, 17, 19, and 25-30 under 35 U.S.C. 102(b) as anticipated by Kwon et al. (1996) Proceed. Natl. Acad. Sci., Vol. 93, pp. 13010-13013 ("Kwon reference").

As the MPEP states in section 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (quoting Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). The MPEP further states in section 2131 that "[t]he *identical invention* must be shown in as complete detail as is contained in the ... claim." (emphasis added) (quoting Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1990)).

Applicant respectfully submits that the Kwon reference does not teach or suggest "each and every element" of the claimed invention as amended. Specifically, the Kwon reference fails to teach or suggest the use of genetic material from differentiated cells for the production of cloned embryos. Rather, the Kwon reference is directed to "the production of genetically identical mice by the transfer of metaphase-stage nuclei from four-cell [undifferentiated] embryos." (emphasis added) (citing the Kwon reference Col. 1, page 13010). The Office Action

appears to acknowledge this point, because the rejection does not extend to former claim 6, which required that the donor genetic material be derived from a differentiated cell.

Based upon this distinction, Applicant respectfully requests withdrawal of the anticipation rejection over Kwon.

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action also rejects:

- Claims 1 and 23 as obvious over Prather et al. (1989) Biology of Reproduction, Vol. 41, pp. 414-418 ("Prather reference") in view of the Kwon reference;
- Claims 1, 6, 7, 9, 10, and 24 as obvious over Cibelli et al. (1998) Science, Vol. 280, pp. 1256-1258 ("Cibelli reference") in view of the Kwon reference;
- Claims 1, 6-10, and 24 as obvious over Wakayama et al. (1998) Nature, Vol. 394, pp. 369-374 ("Wakayama reference") in view of the Kwon reference;
- Claims 1 and 11-13 as obvious over the Kwon reference in view of Campbell et al. (1994) Biology of Reproduction, Vol. 50, pp. 1385-1393 ("Campbell reference"); and
- Claims 1, 11, and 18 as obvious over the Kwon reference in view of Yang et al. (1992) Biology of Reproduction, Vol. 46, Suppl. No. 1, page 117, Abs. 268 ("Yang reference").

As the MPEP states in section 2142, for a combination of references to establish a *prima facie* case of obviousness under 35 U.S.C. 103, three basic criteria must be met:

> *First*, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. *Second*, there must be a reasonable expectation of success. *Finally*, the prior art reference (or references when combined) must *teach or suggest all the claim limitations*. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (emphasis added).

Prather in view of Kwon

The combination of Prather and Kwon does not support a prima facie case of obviousness against claims 1 and 23 because the references when combined do not teach or suggest all of the claimed limitations. In particular, nothing in the references teaches or suggests the use of differentiated metaphase cells for the donor genetic material. Rather, Prather teaches the use of a pig 2-, 4 or 8-cell embryo as the donor genetic material, and Kwon teaches the use of 4-cell embryos as the donor genetic material. In fact, the references teach against the use of differentiated cells for the donor genetic material. As stated by Prather at page 416, "[a] major developmental difference between these animal embryos is the timing of the transition from maternal control of development (relying upon maternally stored RNA) to zygotic control of development (relying upon zygotically produced RNA)." In view of these differences, Applicant respectfully submits that the combination of Prather and Kwon does not support a prima facie case of obviousness against claims 1 and 23.

Cibelli in view of Kwon

Cibelli in view of Kwon does not support a prima facie case of obviousness against claims 1, 6, 7, 9, 10, and 24 because there is nothing in these references to suggest that metaphase donor genetic material from a differentiated cell could be successfully used as the source of genetic material in a nuclear transfer operation. The Office Action states that it would have been obvious to use metaphase genetic material in Cibelli's method of nuclear transfer, which employed differentiated cells, based on Kwon's "teaching [that] synchronized donor and recipient cells results in a 27% success rate over Cibelli's 14% success rate."

However, there is no suggestion in any of these references that the cells could be both differentiated and in metaphase, and still give rise to a successful nuclear transfer. To the contrary, Kwon expresses a clear preference for undifferentiated donor genetic material at the 4-cell stage, and Cibelli states on page 1257, col. 3, par. 3 that "more work will be necessary to understand the properties of somatic cells required to allow for successful reprogramming and full term development of offspring."

It is worth noting that Cibelli was published two years after Kwon, and drew no conclusions from Kwon that metaphase genetic material could be used in Cibelli's method. The relative success rates of Kwon and Cibelli do not cure these deficiencies because Kwon was using 4-cell stage donor cells, and Cibelli was using somatic cells, and a worker of ordinary skill would most likely attribute the difference in success rates to this difference, rather than any differences in cell cycle stage for the donor cell.

In view of these deficiencies in the prior art, Applicant respectfully submits that the combination of Cibelli and Kwon does not support a prima facie case of obviousness.

Wakayama in view of Kwon

Wakayama in view of Kwon also does not support a prima facie rejection of claims 1, 6-10, and 24. This combination suffers from the exact same deficiency as Cibelli in view of Kwon, because there is nothing in these references to suggest that metaphase donor genetic material from a differentiated cell could be successfully used as the source of genetic material in a nuclear transfer operation. Kwon expresses a clear preference for undifferentiated donor genetic material at the 4-cell stage, and Wakayama states a clear preference for G0 or G1 donor genetic material. As stated by Wakayama on page 369, col. 2, "[p]revious studies have suggested that embryonic development is enhanced when donor nuclei are in the G0 or G1 phase of the cell cycle. [Based on these studies, we] have investigated the development potential of oocytes injected with the nuclei of non-cultured cells known to be at G0."

Once again, Wakayama was published two years after Kwon, and drew no conclusions from Kwon that metaphase genetic material could be used in Wakayama's method. The relative success rates of Kwon and Wakayama do not cure these deficiencies because Kwon was using 4-cell stage donor cells, and Wakayama was using somatic cells, and a worker of ordinary skill would most likely attribute the difference in success rates to this difference, rather than any differences in cell cycle stage for the donor cell.

Kwon in view of Campbell

Kwon in view of Campbell does not support a prima facie rejection of claims 1 and 11-13, in view of the amendment of claim 1 to require a differentiated donor cell. The "differentiated" limitation was previously present in claim 6, and the Office Action does not assert a prima facie rejection against claim 6 based on this combination of references.

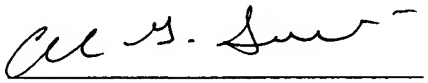
Kwon in view of Yang

Kwon in view of Yang also does not support a prima facie rejection of claims 1, 11 and 18, in view of the amendment of claim 1 to require differentiated donor cell. The "differentiated" limitation was previously present in claim 6, and the Office Action does not assert a prima facie rejection against claim 6 based on this combination of references.

CONCLUSION

No fees are believed to be due in connection with this Response to Non-Final Office Action. The Commissioner is hereby authorized to charge any underpayment of fees to Deposit Account No. 11-0980. If any issues exist that can be resolved with an Examiner's Amendment or a telephone conference, please contact Applicant's undersigned attorney at (404) 572-3513.

Respectfully submitted,



Clark G. Sullivan
Reg. No. 36,942

KING & SPALDING LLP
1180 Peachtree Street, N.E.
Atlanta, Georgia 30309-3521
Phone: (404) 572-3513
Fax: (404) 572-5134

Date: February 27, 2007